

In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-49 (Previously cancelled)

50. ~~(Cancelled) A pharmaceutical composition for treating autoimmune disease comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; and wherein said agent has an effect on GM-1 mediated intracellular signaling events.~~

51. ~~(Cancelled) A composition according to claim 50 wherein said agent is selected from the group consisting of Etx, EtxB, and antibodies capable of binding GM1.~~

52. ~~(Cancelled) A composition according to claim 50 wherein said agent is EtxB.~~

53. ~~(Cancelled) A pharmaceutical composition according to claim 50 wherein said pharmaceutical composition further comprises an effective amount of antigen.~~

54. ~~(Cancelled) The pharmaceutical composition according to claim 53 wherein said antigen further comprises a self or cross reacting antigen.~~

55. ~~(Cancelled) A composition according to claim 50 wherein said autoimmune disease is already in progress.~~

56. ~~(Cancelled) A composition according to claim 50 wherein the pharmaceutical composition is for the prevention of the onset of a disease.~~

57. (Cancelled) ~~A composition according to claim 53 wherein the antigen is insulin.~~
58. (Cancelled) ~~A composition according to claim 53 wherein the antigen is GAD.~~
59. (Cancelled) ~~A composition according to claim 53 wherein the antigen is an islet associated antigen.~~
60. (Cancelled) ~~A pharmaceutical composition according to claim 50, wherein said pharmaceutical composition is in the form of a lotion, a solution, a cream, an ointment, a dusting powder, a skin patch, a nasal spray, an aerosol, an injectable, a pessary, a suppository, a tablet, or a capsule.~~
61. (Cancelled) ~~A pharmaceutical composition according to claim 50 further comprising at least one preservative.~~
62. (Cancelled) ~~A pharmaceutical composition according to claim 50, wherein said composition is adapted for systemic administration.~~
63. (Cancelled) ~~A pharmaceutical composition according to claim 50, wherein said composition is adapted for oral, injection, topical, inhalation, parenteral, mucosal, intramuscular, intravenous, subcutaneous, intraocular, or transdermal administration.~~
64. (Cancelled) ~~A pharmaceutical composition according to claim 51, wherein said composition is adapted for oral, injection, topical, inhalation, parenteral, mucosal, intramuscular, intravenous, subcutaneous, intraocular, or transdermal administration.~~
65. (Cancelled) ~~A pharmaceutical composition for treating autoimmune disease selected from the group consisting of diabetes, arthritis and multiple sclerosis comprising~~

~~an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein if said agent is for coadministration with an antigen, then the agent and the antigen are not so linked to form a single active agent.~~

66. (Cancelled) ~~A pharmaceutical composition for treating diabetes comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein if said agent is for coadministration with an antigen, then the agent and the antigen are not so linked to form a single active agent.~~

67. (Cancelled) ~~A pharmaceutical composition for treating autoimmune disease comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein if said agent is for coadministration with an antigen, then the agent and the antigen are not so linked to form a single active agent.~~

68. (Cancelled) ~~A pharmaceutical composition for treating autoimmune disease comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-~~

~~1 mediated intracellular signaling events; and wherein the pharmaceutical composition further comprises an antigen, wherein the agent and the antigen are not so linked to form a single active agent.~~

69. (New) A pharmaceutical composition for treating diabetes comprising an effective amount of self-antigen for diabetes; and EtxB, wherein EtxB has an effect on ganglioside GM-1 mediated intracellular signaling events and is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease.

70 (New) The composition according to claim 69 wherein the self-antigen for diabetes is GAD.

71. (New) The composition according to claim 69 wherein the self-antigen for diabetes is insulin.

72. (New) The composition according to claim 69 wherein EtxB and the self-antigen for diabetes are not so linked to form a single active agent.

73. (New) The composition according to claim 69 wherein the self-antigen for diabetes is an islet associated antigen.

74. (New) The composition according to claim 69 wherein the pharmaceutical composition is further characterized as a prophylaxis.

75. (New) The pharmaceutical composition according to claim 69, wherein said pharmaceutical composition is in the form of a lotion, a solution, a cream, an ointment, a dusting powder, a skin-patch, a nasal spray, an aerosol, an injectable, a pessary, a suppository, a tablet, or a capsule.

76. (New) The pharmaceutical composition according to claim 69 further comprising at least one preservative.

77. (New) The pharmaceutical composition according to claim 69, wherein said composition is adapted for systemic administration.

78. (New) The pharmaceutical composition according to claim 69, wherein said composition is adapted for oral, injection, topical, inhalation, parenteral, mucosal, intramuscular, intravenous, subcutaneous, intraocular, or transdermal administration.

79. (New) A pharmaceutical composition for treating diabetes comprising a self-antigen for diabetes, and EtxB, wherein said EtxB is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease, and wherein said EtxB has an effect on ganglioside GM-1 mediated intracellular signaling events, with the proviso that if said self-antigen for diabetes is for coadministration with EtxB, then the self-antigen for diabetes and EtxB are not so linked to form a single active agent.

80. (New) The composition according to claim 79 wherein the self-antigen for diabetes is GAD.

81. (New) The composition according to claim 79 wherein the self-antigen for diabetes is insulin.

82. (New) The composition according to claim 79 wherein the self-antigen for diabetes is an islet associated antigen.

83. (New) The composition according to claim 79 wherein the pharmaceutical composition is further characterized as a prophylaxis.

84. (New) The pharmaceutical composition according to claim 79, wherein said pharmaceutical composition is in the form of a lotion, a solution, a cream, an ointment, a dusting powder, a skin-patch, a nasal spray, an aerosol, an injectable, a pessary, a suppository, a tablet, or a capsule.

85. (New) The pharmaceutical composition according to claim 79 further comprising at least one preservative.

86. (New) The pharmaceutical composition according to claim 79, wherein said composition is adapted for systemic administration.

87. (New) The pharmaceutical composition according to claim 79, wherein said composition is adapted for oral, injection, topical, inhalation, parenteral, mucosal, intramuscular, intravenous, subcutaneous, intraocular, or transdermal administration.